EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CELGENE CORPORATION,
Plaintiff,
v.
HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, HETERO USA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, APOTEX INC., APOTEX CORP., MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN, N.V., BRECKENRIDGE PHARMACEUTICAL, INC., and TEVA PHARMACEUTICALS USA, INC.,
Defendants.

Case No: 2:17-cv-03387 (ES)(MAH)
CONSOLIDATED

VIDEO DEPOSITION OF
Kinam Park, Ph.D.
June 7, 2019
New York, New York
Lead: Frank Calvosa, Esquire
Firm: Quinn Emanuel Urquhart & Sullivan

FINAL COPY
JANE ROSE REPORTING 1.800.825.3341

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P R O C E E D I N G

Friday, June 7, 2019

New York, New York

9:35 a.m.

* * *

THE VIDEOGRAPHER: Here begins media No. 1, Vol. I, in the deposition of Dr. Kinam Park, in the matter of Celgene Corporation versus Par Pharmaceutical, Inc., et al.

Today's date is June 7, 2019, and the time is 9:35 a.m.

This deposition is being taken at Kirkland & Ellis LLP, New York, New York.

I am Ingrid Rodriguez, the videographer, and the court reporter is Brad Rainoff, from Jane Rose Reporting, New York, New York.

Will counsel please state your appearances for the record?

MR. CALVOSA: Frank Calvosa from Quinn Emanuel Urquhart & Sullivan, LLP on behalf of plaintiff Celgene.

With me is Brian Forsatz and Geoff Kirsner, also of Quinn Emanuel.

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And on behalf of Celgene also, Matthew J. Hertko from Jones Day on behalf of Celgene.

And also present is Steve Little.

MR. JAGOE: Where is Steve Little from? Who is Steve Little?

MR. CALVOSA: He's our expert in the case.

MR. JAGOE: Oh, okay.

I'm Christopher Jagoe from Kirkland & Ellis representing Teva and the witness.

And with me from Kirkland are colleagues Mark McLennan, Ashley Cade, and Yang Li, who is not an attorney yet.

MS. HANSON: Kristina Hanson from Wilson Sonsini Goodrich & Rosati on behalf of the Mylan defendants and the witness.

KINAM PARK, Ph.D.,

having been duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. CALVOSA:

Q. Good morning, Dr. Park.

A. Good morning.

Q. You already said your name for the record.

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Can you say your business address?

A. Purdue University, School of Biomedical Engineering, West Lafayette, Indiana 40907.

MR. CALVOSA: I'm going to hand you what I have marked as Park 1 and Park 2.

* * *

(Exhibit Park 1, Multipage document entitled: Declaration of Dr. Kinam Park, Ph.D., dated November 15, 2018 (no Bates Nos.), marked for identification)

* * *

(Exhibit Park 2, Multipage document entitled: Supplemental Declaration of Dr. Kinam Park, Ph.D., dated May 29, 2019 (no Bates Nos.), marked for identification)

* * *

BY MR. CALVOSA:

Q. Just take a look at Park 1.

Do you understand Park 1 to be your declaration that was submitted in this case concerning certain terms of U.S. Patent Nos. 8,198,262, which I'll refer to as "the '262 patent," 8,673,939, which I'll refer to as "the '939 patent," 8,735,428, which I'll refer to as

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"the '428 patent," and 8,828,427, which I'll refer to as "the '427 patent"?

A. Yes.

Q. If you turn to the last page -- page 34 -- is that your signature there?

A. Yes.

Q. You signed this declaration on November 15, 2018?

A. Yes.

Q. Did you review this declaration in preparation for your deposition today?

A. Yes, I did.

Q. Did you come across any mistakes or inaccuracies that you would like to correct at this time?

A. Not that I found, nothing.

Q. If you take a look at Park 2 -- which is titled: Supplemental Declaration of Dr. Kinam Park, Ph.D. -- is this the declaration you submitted concerning the claim term "lubricant" from United States Patent No. 9,993,467, which I'll refer to as "the 467 patent"?

A. Yes.

Q. If you turn to the last page again -- page 14 -- is that your signature there?

A. Yes.
Q. You signed this declaration on May 29, 2019, right?
A. Right.
Q. Are you represented by counsel here today?
MR. JAGOE: Yes, he is.
BY MR. CALVOSA:
Q. And that would be Mr. Jagoe, to your right?
MR. JAGOE: At least.
A. Yes.
MR. CALVOSA: When you say "at least," what do you mean?
MR. JAGOE: Well, I heard somebody else --
MS. HANSON: The Mylan defendants have also retained Dr. Park.
MR. CALVOSA: Okay.
Anybody else?
BY MR. CALVOSA:
Q. Dr. Park, have you been retained by any defendants in this matter other than Mylan and Teva?
A. In this case?

Q. In this case.
(Pause)
A. I think other firms that retained me also include Aurobindo and Hetero.
Q. So you have been retained by Teva, Mylan, Aurobindo, and Hetero.
Is that right?
A. Yes.
And I also recall Apotex, but I'm not sure that I had retained a letter or not.
Q. What about Breckenridge?
A. That is also a part of the talk, but I don't recall whether I have retained a letter signed or not.
Q. Were any attorneys from Breckenridge present in any preparation you did for your deposition today?
A. I don't recall, but -- not here yesterday.
Q. Were they on the phone?
A. Some lawyers were on the phone.
Q. Were any lawyers from Breckenridge on the phone?
A. That's what I don't remember.
Q. Were any lawyers from Apotex on the

phone?
A. I actually don't remember because I don't recall the names.
Q. Have you been deposed before?
A. Yes.
Q. About how many times?
A. I don't recall, but about anywhere between 10 and 20 times.
Q. So I'm sure you might know, but just some simple grounds rules for the day.
I'm going to be asking a series of questions. Your counsel may object from time to time.
I ask that you wait for me to finish my question, wait for him to finish his objection. That way nobody is talking over each other.
But unless Mr. Jagoe instructs you not to answer, you do have to answer my question.
You could take a break at any time you like, just let me know.
I just ask that if a question is pending, you answer that question and then we are free to break.
In those 10 to 20 times you have been

deposed, were you serving as an expert in the cases?
A. Yes.
Q. Were they all patent cases?
A. I think so.
Q. Have you heard the phrase "ANDA case" before?
A. Yes.
Q. What do you understand an ANDA case to be?
A. Well, "ANDA" means Abbreviated New Drug Application, so ANDA application by generic companies.
Cases usually involve the patents associated with a particular drug.
Q. And you understand it to be ANDA cases oftentimes between the -- the litigation between the patent holder and the generic drug companies?
A. That is my understanding.
Q. Those 10 to 20 times you appeared as an expert for depositions -- were those all in ANDA cases?
A. Not all of them.
Q. About how many of them were ANDA

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cases?
A. Majority of them.
Q. In the ones that were ANDA cases, did you testify for the patent holder or the generic company?
A. Both.
MR. JAGOE: Compound.
A. Both.
(Pause)
Q. Could you turn to Park 1, your background and qualifications section that begins on page 2, paragraph 6?
A. Yeah.
Q. You say here that you are currently the Showalter Distinguished Professor of Biomedical Engineering, as well as a full professor in the department of pharmaceutics at Purdue University.
Do you see that?
A. Yes.
Q. What is the Showalter Distinguished Professor?
A. Each university has a rank called distinguished professor, which is official rank above full professor. Many times such a

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distinguished professor position comes with some endowment.
And in this case, Showalter foundation provide the money to -- as an endowment fund. So it's called Showalter Distinguished Professor.
Q. When you use "Biomedical Engineering" here in paragraph 6 of your declaration, what do you mean by that term?
A. Biomedical Engineering is the name of the department; also sometimes called the School of Biomedical Engineering as -- at Purdue University.
The full name is the Showalter Distinguished Professor of Biomedical Engineering because it was given by the Weldon School of Biomedical Engineering.
Q. So for biomedical engineering -- I guess the department -- what is that?
A. You are asking me what is biomedical engineering?
Q. Yes. I just don't know, so curious about that.
A. You are asking me: What is biomedical engineering?

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MR. JAGOE: At Purdue.
BY MR. CALVOSA:
Q. Yes.
A. At Purdue? Or in general?
Q. Is there a difference?
A. Sometimes some department called bioengineering, biomedical engineering -- so depending on how you call it.
At Purdue University, biomedical engineering means applying engineering discipline to the issues related to biomedical and pharmaceutical field, vice versa.
Q. What does it mean to apply engineering to, for example, the pharmaceutical field?
A. Well, the pharmaceutical field deals with a variety of different disciplines, starting from making formulation, applying it to patients, measuring throughout concentration in blood, which we call pharmacokinetics, and applying engineering principles to design and develop new drug delivery systems.
(Pause)
Q. When you say here "the Department of Pharmaceutics," what is the department of pharmaceutics at Purdue University?

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A. "Pharmaceutics" indicates formulation development in pharmacokinetics, pharmacodynamics, formulation including variety of different drugs -- water soluble drugs, water insoluble drugs -- large molecular weight drugs, including peptide and proteins, stability study -- a number of different aspect of drug development.
Q. You have used the word "formulation" a couple times.
And one time, you said "formulation development"; another time you said "making formulation."
What do you mean by "formulation"?
A. Simply for formulation refers to drug delivery system which can be tablet, capsules, injectables, solutions, IV solution, eyedrops -- all different types of drug delivery system.
Q. Was that a comprehensive list that you gave of different drug delivery systems for formulations?
A. No.
Q. Are there many more?
A. Yes.
(Pause)

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Q. If you turn the page in part I to page 3 of paragraph 8.
(Pause)
Q. -- that first sentence there, you say that your expertise relates generally to the development of human pharmaceuticals for the treatment of various conditions.
Do you see that?
A. Yes.
Q. When you use "development of human pharmaceuticals," do you mean the same thing as "formulation"?
A. Yeah, formulation designed to use in humans.
Q. Have you, yourself, ever developed a human pharmaceutical?
A. I have been developing many formulation for human applications.
Q. Are any of those formulations marketed today?
A. Not yet.
(Pause)
Q. When we talk about a formulation, it has or could have different ingredients in there, right?

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MR. JAGOE: Objection to form.
A. Formulation could have a different ingredients.
Is that the question?
Q. Yes.
A. Yes.
Q. Two of the terms that I've seen you use -- and I think they are general terms -- one is "active ingredient" could be in formulation?
Is that right?
A. Active ingredients, you mean drug itself.
Q. Is that what you mean by active ingredient?
MR. JAGOE: Objection to form.
A. It's my understanding when one said "active pharmaceutical ingredient," it means drug.
Q. Then another term we have seen used is "inactive ingredients."
What do you mean by that?
A. Formulation has two ingredients; one is drug and the rest of it called inactive ingredient.
(Pause)

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Q. Do inactive ingredients have any activity?
A. Otherwise, you don't call it active ingredient.
Q. I think you might have misheard my question.
Do inactive ingredients have any activity?
MR. JAGOE: Objection, lacks foundation, and objection to form.
A. Are you talking about inactive ingredient in a formulation?
Q. In a formulation, yes.
A. Any specific formulation?
Q. No specific formulation.
A. So the question was: Inactive ingredient has any activity?
Q. Yes.
A. I don't think so.
Q. Why do you say: I don't think so?
A. If an inactive ingredient has an activity, we may not probably call it inactive ingredient.
Q. How do you understand the term "activity"?

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MR. JAGOE: Objection, vague, form.
A. Activity of what?
Q. Well, I asked you whether inactive ingredients have any activity.
And you said: If an inactive ingredient has an activity, we may not probably call it inactive ingredient.
A. Right.
Q. So how did you understand "activity" when you were answering that question?
A. We are talking about drug formulation -- active ingredient, which is a drug. So drug had a certain activity. That's why we call it drug.
Q. So what do you mean by "activity" when you say the active pharmaceutical ingredient has activity?
A. For example, aspirin has an activity of a lowering temperature. That's activity.
(Pause)
Q. So when you say that an active pharmaceutical ingredient has activity, you mean that it will have some effect in the human body, right?
A. Some intended effect.

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(Pause)
Q. I think I understand the activity now.
So inactive ingredients have functions?
A. Inactive ingredients have their individual functions.
Q. And those functions are in the formulation as opposed to in the body, right?
MR. JAGOE: Objection to form.
A. I'm not quite sure what you mean.
Q. Well, you seem to be drawing a distinction between activity and function when it comes to an active ingredient, so I'm trying to understand what that is.
MR. JAGOE: Objection to form.
A. I thought when you say "function," you meant excipients, inactive ingredient.
Q. Yes.
And you told me that inactive ingredients don't have activity.
Do you agree they have function?
So I'm trying to understand what's the difference between "activity" and "function," as you understand the words.
A. Well, your question in the beginning

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was active ingredient. So active ingredient has activity of intended bioactivity.
And later, you asked me about inactive ingredients. Yeah, each inactive ingredient has its function. That's why formulation scientists add certain inactive ingredients, which you also call excipients.
Q. When you say that "each inactive ingredient has its function," do you mean that each inactive ingredient has one function?
MR. JAGOE: Objection to form.
And this is outside the scope of the declaration.
So if you want a tutorial from Dr. Park, he's not giving it on behalf of Teva.
A. Did I mention anything about it in my report?
Q. I'm just asking you now. You said: Each ingredient -- each -- sorry, let me start again -- each inactive ingredient has its function.
Do you mean that each inactive ingredient has only one function?
MR. JAGOE: Objection to form.
And if it's not tied to the

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formulations in this case, it has nothing to do with -- you are not answering on behalf of an expert for Teva.
(Pause)
A. Unless it is in my report, I will probably need to know more specifics before giving you an answer.
Q. Well, for example, if we look at -- do you know what the Handbook of Pharmaceutical Excipients is?
A. Yes, I do.
Q. Ask the -- may I call it "the HPE"? Is that okay with you?
A. Sure.
Q. Does the HPE list out different inactive ingredients?
A. Yes, it does.
Q. Does it provide a section for each of those inactive ingredients that talks about the function?
A. Yes, it does.
Q. Does the HPE only list one inactive -- sorry.
Start again.
Does the HPE only list one function

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for each inactive ingredient?
MR. JAGOE: Objection, compound.
Can you show him the HPE if you want to ask him questions about it?
A. I would like to see exactly what section of the HPE you are talking about.
Can you show me any copy of HPE?
Q. You need to see the HPE to tell me whether, for each inactive ingredient listed in the HPE, it lists only one function?
A. I don't remember the whole HPE itself. So if you can show me specific section, or copy of a chapter, let's talk about that then.
Q. That's not what I'm asking you.
I'm asking you -- well, let me ask you this way: How many times in your career have you looked at the HPE?
A. Many times.
Q. About how many?
Ten?
A. I don't recall.
Q. More than 10?
A. I don't recall.
Q. Dr. Park, how long have you been a formulator for?

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A. Too long.
Q. Too long, right?
A. Thirty-three years.
Q. That's right.
Have you ever testified in court that you have been doing this for 30 years and have looked at the HPE thousands and thousands of times?
A. I'm not sure whether I said: Thousands and thousands of times. I don't think so.
Q. Okay.
Based on your memory of looking at the HPE over the last 33 years, you can't tell me for even one inactive ingredient in there whether it lists multiple functions for inactive ingredient?
A. Again, it is not in my report.
And if you want to talk about that particular HPE, I really like to see the section you are talking about.
Q. We'll look at it later.
My question is: Based on your memory of looking at the HPE over the last 33 years, you can't tell me for even one inactive

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ingredient in there whether it lists multiple functions for that inactive ingredient?
A. Again, as I said before, if something you are asking is not in my report, I would like to see some HPE itself, or at least a copy of it, so then we can talk about it.
Q. Are you refusing to answer my question?
MR. JAGOE: He answered your question.
A. I don't have any copy of the handbook you are talking about, so I cannot answer.
Q. Well, that's the whole point. The question is based on your memory.
And if the answer is "no," that's fine. But I would like an answer to my question, please.
MR. JAGOE: He answered the question.
BY MR. CALVOSA:
Q. Based on your memory of looking at the HPE over the last three years, you can't tell me for even one inactive ingredient in there whether it lists multiple functions for that inactive ingredient?
A. Well, again, in the absence of actual HPE -- if I have actual handbook, I can talk

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about it. But I cannot talk from my memory, okay? And it's not in my report either.
So please show me the handbook.
Q. Okay.
I just want to have it clear.
You don't remember whether any inactive ingredient listed in the HPE has more than one function listed for that inactive ingredient?
MR. JAGOE: Asked and answered.
A. I simply asked to see the actual handbook before answering.
Q. I'll show it to you, but I want an answer to my question first.
Without the handbook, you don't remember whether any inactive ingredient listed in the HPE has more than one function listed for that inactive ingredient?
MR. JAGOE: Asked and answered.
A. If you have a handbook, show me first and I will answer.
Q. I will show you after. I would like -- the question is without the handbook.
MR. JAGOE: Move on. You are not going to get an answer. So you don't have to

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say any more.
You have answered it five times.
Move on.
MR. CALVOSA: If you want to move for a protective order, I'm happy to have Judge Hammer and Judge Salas on the phone to listen to this.
MR. JAGOE: I'm not moving for a protective order --
MR. CALVOSA: Fine.
MR. JAGOE: -- I'm telling you to move on to another question.
MR. CALVOSA: Oh, no. I'm going to ask this over and over.
MR. JAGOE: Go ahead.
You don't have to respond.
MR. CALVOSA: Yes, he does. You know he does.
MR. JAGOE: I know he doesn't.
MR. CALVOSA: You have a case that says that?
You have move for a protective order. If you don't want to do that, I'm going to ask the same question.
MR. JAGOE: Keeping asking, but he's

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not going to respond.
MR. CALVOSA: He has to respond.
BY MR. CALVOSA:
Q. Without the HPE in hand, you don't remember whether any inactive ingredient listed in the HPE has more than one function listed for that inactive ingredient?
MR. JAGOE: You don't have to respond beyond what you have already said.
MR. CALVOSA: He has to answer the question.
MR. JAGOE: He did.
MR. CALVOSA: Are you going to move for a protective order?
MR. JAGOE: No.
MR. CALVOSA: Then you can't put speaking objections on the record, or else we are going to move for sanctions.
MR. JAGOE: You are abusing the witness.
MR. CALVOSA: No, I'm not.
MR. JAGOE: Yes, you are.
MR. CALVOSA: I can't get an answer to my question.
MR. JAGOE: You have asked the same

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question five times, and he responded five times. You are not going to keep asking the same question.
MR. CALVOSA: I have seven hours. I'll ask the same question over and over.
MR. JAGOE: Okay, and you'll get the same answer.
MR. CALVOSA: That's fine.
MR. JAGOE: So you don't have to respond beyond what you already said.
MR. CALVOSA: He has to respond to the question.
MR. JAGOE: Not beyond what he already said.
BY MR. CALVOSA:
Q. Dr. Park, without the handbook in front of you, you don't remember whether any inactive ingredient listed in there has more than one function listed for that inactive ingredient?
A. That's not what I said.
I simply said Handbook of Pharmaceutical Excipient is a big book. So if you want to talk about a specific section of the book, show me the book exactly what you are

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talking about.
Q. If you don't want to answer, that's fine.
(Pause)
Q. In paragraph 8, last sentence, you say, for example -- this is Park 1: For example, I have extensive research experience in oral drug delivery formulations ranging from fast dissolving tablets to gastric retention formulations using commonly known pharmaceutical excipients as well as newly synthesized polymers and hydrogels for sustained drug delivery applications.
Do you see that?
A. Yes.
Q. What is one example of a commonly known pharmaceutical excipient?
(Pause)
A. Like carboxymethyl cellulose.
(Pause)
Q. You said carboxy --
A. -- methyl cellulose, CMC.
Q. CMC.
What is the function of CMC?
A. CMC, as I recall, can be used as a

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filler or diluent, for example.
Q. You said: For example.
Does it have other functions?
A. Sometimes it may use binder, but that depends on formulation scientists -- how they are using it.
Q. What do you mean -- "it depends on how the formulation scientist is using it"?
(Pause)
A. Another common excipient is hydroxypropyl methylcellulose. So HPMC -- the formulation scientist decide to use it as a filler, he use larger quantity to use as a filler. So depending on formulation scientist, they define a main function.
(Pause)
Q. So the main function of -- here use HPMC as the example -- is defined based on how the formulation scientist wants to use it?
MR. JAGOE: Objection, form.
A. Some formulation scientists, yeah, decide to use one excipient for certain application, certain function.
Q. So for the HPMC, if the formulation scientist decides to use it as a filler, it's a

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filler, in your opinion?
A. In that formulation.
Q. And if the pharmaceutical -- sorry.
If the formulation scientist decides to use the HPMC as a binder in a specific formulation, then it's a binder in that formulation, in your opinion?
A. That's what the formulation scientist use it as a binder.
Q. What if the formulation scientist decides to use HPMC as, say, a disintegrant in a formulation?
Does that make it a disintegrant in that formulation?
MR. JAGOE: Objection to form, incomplete hypothetical.
A. Each formulation is very different, so I need to know exactly what formulation ingredient you are talking about -- not only that, how you make it. Only then I can tell you what the real function is.
Q. Why is that?
Why do you need to know what the formulation is and how it's made to determine the function?

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A. Otherwise simply having a certain ingredient does not tell me exactly how it function.
Q. So you need to see the actual function in the formulation of the inactive ingredient to determine how it functions?
MR. JAGOE: Objection, mischaracterizes.
A. I like to see the overall ingredients and how a formulation is made. Then I can tell you what each function of each ingredient is.
Q. In certain formulations, it's possible for the formulator to use one ingredient to serve two different functions, right?
MR. JAGOE: Objection, incomplete hypothetical.
A. Again, I don't know what specific example you are talking about.
But each formulation, one ingredient has one function.
Q. I think I understand better.
So for any given formulation, one inactive ingredient will only have one function?
A. Well, again, it's too general.
But that's why formulation scientist

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will write down individual ingredient and specify its function.
(Pause)
Q. Are you familiar with dextrose?
A. You mean carbohydrate?
Q. Yes.
A. Yes.
Q. Do you remember, sitting here today, what the function is of dextrose?
A. I don't recall all of them, but dextrose is used to make a solution formulation for injectables.
I don't recall all its function.
Q. Okay.
(Pause)
MR. CALVOSA: Handing you what I have marked as Park 3.
* * *
(Exhibit Park 3, Multipage document entitled: Handbook of Pharmaceutical Excipients, Sixth edition: Dextrose (no Bates Nos.), marked for identification)
* * *
MR. CALVOSA: I'll represent to you that this is the entry for dextrose for the

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pharmaceutical -- or, sorry -- for the Handbook of Pharmaceutical Excipients, Sixth edition, from 2009.
(Pause)
THE WITNESS: Yes.
BY MR. CALVOSA:
Q. Is this the -- is this -- sorry.
Is an entry like this from the HPE something you are familiar with?
(Pause)
A. Yes.
Q. The HPE is something that, in your opinion, a POSA would be familiar with?
A. I think so.
Q. On page 222 here of Park 3, there is --
A. Page 222?
Q. 222, yeah.
For dextrose, there is a bold heading that says: 6: Functional Category?
A. Yes.
Q. It lists more than one function for dextrose, right?
(Pause)
A. Yes.

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Q. And it lists: Diluent, therapeutic agent, tonicity agent, and sweetening agent. Right?
A. That's what it says.
MR. JAGOE: It says "tablet and capsule diluent," to be precise.
A. That's right. You simply said "diluent," but it says "tablet capsule diluent."
Q. Sure, tablet and capsule diluent. Have you ever used dextrose to formulate tablets in your 33 years of experience?
MR. JAGOE: You don't have to disclose any proprietary information that would be confidential to any other party, but I guess you can answer yes or no.
A. Yes.
Q. What was the function of the dextrose in the formulation you made?
A. Sweetening agent.
(Pause)
Q. How did you determine that the function of dextrose in the formulation you made was a sweetening agent?
A. In my case, I used glucose to make a

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tablet sweet, so it is sweetening agent in my formulation.
Q. So you determined the function was a sweetening agent because of how you used it in the formulation, right?
A. That's right.
(Pause)
Q. Did the dextrose have any other function in the formulation that you made it in?
(Pause)
A. The other case I used as a therapeutic agent.
Q. Sorry. My question wasn't clear. In the specific formulation we were just you talking about where you used it as a sweetening agent, did the dextrose have any other function other than being a sweetening agent?
A. No.
Q. Is it possible that it had another function other than being a sweetening agent?
A. I'm not sure what you mean by: It's possible. Can you give me a specific example?
Q. Sure.

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So in that specific formulation we were talking about, did you do any tests to confirm that it was a sweetening agent?
A. Did I test it to confirm it was a sweetening agent?
Q. Yes.
A. When you put it in your mouth, it's sweet, so it's a sweetening agent.
Q. Did you actually carry out that test and try it and confirm it was sweet?
A. Myself?
Q. Yes.
A. Of course.
Q. Okay. Do you self-administer every formulation you make?
A. No.
(Pause)
Q. What made you do it with this one?
A. This was for a fast-dissolving tablet containing bitter-tasting caffeine, so I added dextrose to make it sweeter.
(Pause)
Q. What was the total milligram weight of that formulation?

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A. I'm sorry?
Q. What was the total milligram weight of that formulation?
A. Formulation can vary depending on how much you deliver the ingredient you want to. So it can be as mall small as 5-milligram up to 500-milligram.
Q. In that specific formulation where you put dextrose for the fast-dissolving tablet, how many milligrams was that formulation?
A. I don't recall.
Q. What other ingredients were in that formulation other than dextrose and the active?
(Pause)
A. What I say may have caffeine in --
MR. JAGOE: Caffeine.
A. -- caffeine.
(Pause)
A. In other excipients, I don't remember exactly.
Q. In that specific formulation, how much dextrose did you add?
A. It was a while ago, and I just don't recall exactly -- exactly how much excipient I used.

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Q. Do you remember if it was a little bit?
Or a lot?
A. Sweetening agent, depending on formulation, can be small or it can be a larger than, you know, small portion that you may need otherwise.
So I don't recall.
Q. Why would you use a larger amount of sweetening agent in a given formulation?
A. If you use a higher amount of caffeine, for example, you need proportional larger amount of sweetening agent.
Q. Is there any other reason you would use a larger amount of sweetening agent in a given formulation?
A. At this point, I don't see why.
Q. I mentioned the person of ordinary skill of the POSA in one of my questions before.
And you provide a definition for a POSA, if we could look at paragraph 17 of Park 1, and also paragraph 5 of Park 2?
(Pause)
A. Yes.
Q. And I want to focus on -- in paragraph

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17 of Park 1, this is your definition of a POSA for the '427 patent, right?
A. Yes.
Q. In Park 5 -- sorry -- park 2, paragraph 5, you provide a definition of a POSA for the '467 patent.
Is that right?
A. Yes.
Q. And can you just confirm for me that your definition of a POSA for the '467 patent is the same as your definition of a POSA for the '427 patent?
(Pause)
A. Yes.
(Pause)
Q. And I believe you define the '467 and '427 patent --
(Pause)
A. Was there a question to me?
Q. I'll ask a different question.
Is it okay if I refer to your POSA for the '467 patent and '427 patent as "the formulation POSA"?
A. That's fair.
Q. So we could just look at Park 1 -- so

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instead of saying paragraph 17.
How did you come up with your definition of the formulation POSA?
MR. JAGOE: Don't disclose any communications you've had with counsel.
(Pause)
A. Based on my experience, my former students who graduated from Purdue have a Ph.D. degree. They go to industry and actually develop their own formulation. And so this definition is based on my experience.
And also, throughout the observation I have made over the years, this is definition for a POSA for a formulation scientist.
Q. Did you consider the '427 and '467 patents when you were trying to arrive at your definition of a formulation POSA?
A. Could you repeat the question?
Was I aware of two patents before coming up to --
Q. So let me answer the -- in coming up with your definition of the formulation POSA, did you consider the two patents that you opine about here -- the '467 patent and the '427 patent?

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(Pause)
A. Yes, I did.
Q. If you turn to paragraph 16 of Park 1 --
A. Paragraph --
Q. Sixteen -- one page before -- page 5.
(Pause)
Q. I'm looking at the third sentence there where you say: Factors that may be considered in determining the level of ordinary skill in the art may include.
And then you list five different factors.
Do you see those?
A. Yes.
Q. Then you say, after you list the five factors: In a given case, not every factor may be present, and one or more factors may predominate.
Do you see that?
A. Yes.
Q. Did you consider any of the five factors here in paragraph 16 in coming up with your definition of the formulation POSA?
(Pause)

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A. Yeah, this No. 1.
Q. Any others than No. 1?
A. And No. 4.
Q. Any others than 1 and 4?
A. No. 5.
Q. Is there a reason that you didn't consider factors Nos. 2 and 3?
A. I did not say I did not consider.
I said that one or more factors may predominate. So those are factors that predominated, to my mind.
Q. Okay.
I was asking you if you considered the factors, not predominate.
But did you consider factor 2, then?
A. Yes.
Q. Did you consider factor 3?
A. Yes.
Q. Can you tell me what your consideration was for factor 4: The sophistication of the technology?
A. To my, when I reviewed the patents, there was really not much sophistication. Formulation was simply a mixture of excipients at certain ratio.

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Q. What would make a formulation sophisticated, in your opinion?
A. For example, if you have a cancer formulation, that formulation goes to deliver drugs to everywhere in the body. That's where side effect comes.
So if someone comes up with a formulation that mostly direct only to cancer cell, that is really sophisticated formulation.
(Pause)
Q. If the formulations in the ones you just mentioned in the formulation patents that we are talking about here do not have much sophistication, why is it your opinion that the person of ordinary skill in the art would have a Ph.D. in the field related to pharmaceutical sciences and at least one year of experience in pharmaceutical formulation; or a lower level of education, such as a Master's degree, if that person had a higher degree of experience?
A. You still need to be trained in certain area to make a formulation. It's not like anybody can go to the garage and make a tablet or capsule. They have to be trained to know how to handle excipients or active

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ingredients.
And you should be able to make it in such a way that you can get approval from the U.S. Food and Drug Administration.
We are not talking about any tablet can you buy on the street. We are talking about a tablet, capsule, and other formulation that we use. You have to make it sure that they are safe and effective. You require training.
Pharmacists go four years or six years training; and after that, you may have even more training to make sure you know what you are doing.
(Pause)
Q. So someone with just a high school degree and no experience in the pharmaceutical industry wouldn't qualify under your definition of POSA, right?
A. That's right. No, they are not qualified.
Q. Is it your opinion that they couldn't make a formulation like that described in the formulation patents that we are talking about today?
A. I'm sorry. The question -- I forgot

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in the first part of your question.
Q. It's your opinion that you need the qualifications that you mentioned before -- the training -- to make the formulations that we are talking about here today, right?
MR. JAGOE: Objection to form.
A. I think I mentioned what may be a person of ordinary skill in the art. That's why I mentioned, as I explained in my paragraph 17.
Q. Okay.
MR. CALVOSA: Would you like to take a little break?
MR. JAGOE: I would.
MR. CALVOSA: Okay. Let's do it.
MS. HANSON: Two things before we go off the record.
First, to the extent that Mr. Jagoe is objecting outside the scope --
(Pause)
MS. HANSON: To the extent that Mr. Jagoe is objecting as outside the scope and that the testimony is not on behalf of the Teva defendants, the Mylan defendants also join this objection, and would like to do so on a standing basis going forward so that I don't need to

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continually interject.
The other thing I was going to bring up is that we should probably get appearances from those on the phone.
MR. JAGOE: Yes.
You are granting her standing objection?
MR. CALVOSA: Of course.
(Pause)
MR. CALVOSA: It's okay with me.
(Pause)
THE VIDEOGRAPHER: The time now is 10:38 a.m. We are off the record.
(Recess from 10:38 a.m. to 10:54 a.m.)
THE VIDEOGRAPHER: This marks the beginning of tape No. 2. The time now is 10:54 a.m. We are back on the record.
BY MR. CALVOSA:
Q. Welcome back, Dr. Park.
A. Thank you.
Q. During the last session, we talked about inactive ingredients or excipients having certain functions.
Do you remember that?
A. Yes.

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(Pause)
Q. If you go to Park 1, paragraph 46 -- and the span is from page 19 to 20 -- feel free to read the whole thing. I would like to focus on the last sentence.
(Pause)
A. Yes.
Q. You say here: Thus, excipients are sometimes characterized by their function.
And you give certain examples of function of excipients.
Is that right?
A. Yes.
Q. The first one listed there is carriers?
A. Yes.
Q. Would a POSA -- the formulation POSA -- be familiar with a carrier?
A. I think so.
Q. What would the formulation POSA understand a carrier to be?
A. Well, sometimes drug molecule -- drug particles may be too small. Then they can be combined with a larger particle size, which is called carrier. So, depending on drug itself

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properties, one can choose carrier as an excipient.
Q. And the carrier would be combined with the drug product for what purpose?
MR. JAGOE: Objection to form.
A. Again, if, as I mentioned, for example, if drug particles are too small, it's difficult to handle. Then you may resort to bigger particle excipients. Then it carries the drug, so sometimes you use carrier in formulation.
Q. Just so the record is clear, did you say "resort to bigger particle excipients"?
Or "absorb"?
A. Small particle drug can bind to bigger particle, so it can be a physical binding, or certain level of adhesions, physical entrapment -- anyway, just part of the bigger particle.
Q. The second sort of functional classification there for excipients that you have is diluent?
A. Yes.
Q. Would a POSA know what a diluent is?
(Pause)

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A. I think so.
Q. And so it's clear, would a formulation POSA know what a diluent is?
A. I'm sure they know.
Q. What would a formulation POSA understand a diluent to be?
A. Well, diluents are usually used when amount of active ingredients or drug is very small. It is difficult to handle. So you add other excipient called diluent to bulk up the whole volume so it's easier to handle to make a certain size of tablet or capsules.
Q. The third function listed there -- binders -- would a formulation POSA know what a binder is?
A. Oh, absolutely.
Q. And how would a formulation POSA understand binder?
A. For example, sometimes you need to make a granule because granules are easier to flow. So then to make a granules, you sometimes add a binder to make a powder form into granule. So a binder can be used to make granules.
Or sometimes, you just use binder to make a better tablets.

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Q. The fourth one -- fillers -- would the formulation POSA know what a filler is?
A. Yes.
Q. What is a filler?
Or what would a formulation POSA understand a filler to be?
A. Filler is usually used -- exchangeable term as a diluent. So filler is also used to make a certain volume of a formulation.
Q. The next one there -- disintegrants -- would a formulation POSA know what a disintegrant is?
A. Absolutely.
Q. How would a formulation POSA understand disintegrant?
A. Disintegrants are usually hydrophilic polymer excipients that absorb water and swell. In so doing, it breaks up tablets. So it is called disintegrant.
Q. Makes sense.
The next one -- lubricants -- would a formulation POSA know what a lubricant is?
A. Oh, absolutely.
Q. How would a formulation POSA understand lubricant?

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A. Lubricant is used, for example, when you make a tablet, when you compress a tablet using machine, without lubricant, portion of the tablet may stick to dies, toolings, so that you do not produce intact tablet; so you use lubricants.
The lubricants, as you have shown here Handbook of Pharmaceutical Excipient -- they have specific lubricant section. If you have it, we can go through it, too.
There are specific excipients known as a lubricant. And they are used in a very small quantity to make intact tablet. Sometimes it may be used in capsule formulation, too, as necessary.
So lubricant is a specific class of excipients. And they are usually hydrophobic, so they are used in a very low quantity.
Q. And the next one -- solubilizers -- would a POSA know what a solubilizer?
A. Yes.
Q. How would a POSA understand solubilizer?
A. Solubilizer is used to dissolve a certain drug, because many drugs are

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hydrophobic -- meaning they do not dissolve in water quite easily. So you use a solubilizer to aid dissolving such drug in water.
Q. The last one you have listed here is thickeners.
Would a POSA understand -- or would a formulation POSA understand what a thickener is?
A. Yes.
Q. How would a formulation POSA understand thickener?
A. Thickeners are usually used to make sure that the solution formulation has a certain viscosity, so that particles in the formulation does not settle and become aggregate. So there are a variety of different reasons to use thickeners.
Q. Let's go back to the lubricants.
And as I'm sure you know, that's one of the terms that you opined on in your declaration -- Park 2 -- right?
A. Yes.
Q. For that one, you gave a nice, long answer, so let's break it down.
(Pause)
Q. The first part you were talking about

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compressing a tablet using a machine.
You said: Without lubricant, a portion of the tablet may stick to dies, tooling, so that you do not produce intact tablet.
Is that right?
A. Yes.
Q. Using the -- this compression tablet method -- is it possible to make an intact tablet without using a lubricant?
MR. JAGOE: Objection to form, incomplete hypothetical.
A. Is it possible? Well, I don't know. Depending on formulation. Without knowing exact formulation, I cannot say.
Q. Well, I'm telling you there is no lubricant in the formulation.
Is it possible to make an intact tablet using the compression method we just discussed without a lubricant?
MR. JAGOE: Same objection.
A. Again, in the absence of detailed information, it is difficult to answer.
For example, if you have a very low pressure, you may have a different tablet. So I

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need exact details or specific example to answer your question.
(Pause)
Q. Have you ever testified that billions of tablets are made every day, and all of them use a lubricant?
A. Have I testified before whether --
Q. Have you testified in a courtroom the following language: Billions of tablets are made every day and all of them use a lubricant?
A. I don't recall whether I said in a courtroom or not, but that sounds right.
Q. Have you ever testified in a courtroom before, the following: Without a lubricant, you cannot make an intact tablet from a die?
MR. JAGOE: If you have a basis to think he said that under oath, you should show him the transcript.
MR. CALVOSA: I'm just asking if he said it.
He can answer now.
MR. JAGOE: You can't ask the question unless have a basis for asking it.
MR. CALVOSA: I can ask any question I would like.

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MR. JAGOE: Oh, no, you can't.
MR. CALVOSA: It might not be a proper question, but I can ask any question I would like.
MR. JAGOE: No, you can't.
MR. CALVOSA: Yes, I can.
MR. JAGOE: No, you can't.
MR. CALVOSA: Counsel, please. I mean, the speaking objections are crazy.
MR. JAGOE: I just made my objection. You engaged me.
MR. CALVOSA: Okay.
MR. JAGOE: If you have a basis for asking that question, you should show him the transcript.
BY MR. CALVOSA:
Q. Dr. Park, do you recall ever testifying in open court that: Without a lubricant, you cannot make an intact tablet formulation with a die?
MR. JAGOE: You have the right to see the transcript, if he has one, Doctor.
A. Again, I don't recall.
And if you have any documents you can show me, we can talk about it for the details.

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Q. Sure. Thank you for answering my question.
MR. CALVOSA: Can we go off the record for a second?
THE VIDEOGRAPHER: The time now is 11:07 a.m. We are off the record.
MR. JAGOE: I didn't agree to go off the record.
MR. CALVOSA: Okay.
MR. JAGOE: Why are we going off the record?
MR. CALVOSA: That's fine. Go back on the record. I was just trying to do this as a professional courtesy, but --
MR. JAGOE: If you tell me you want to talk off the record, but you can't just go off the record unilaterally.
MR. CALVOSA: If you have an objection which you do, we don't have to.
MR. JAGOE: Tell me why you want to go off the record.
MR. CALVOSA: Because I would like to talk to you and not put it on the record. I would think it would be more productive that way.

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MR. JAGOE: Okay, let's go off the record.
MR. CALVOSA: Do you want to excuse the witness? Or --
MR. JAGOE: Sure.
MR. CALVOSA: We are now off the record.
(Recess from 11:08 a.m. to 11:11 a.m.)
THE VIDEOGRAPHER: The time now is 11:11 a.m. We are back on the record.
BY MR. CALVOSA:
Q. Dr. Park, have you ever made a tablet using the compression method we are talking about without using lubricant?
A. We are talking about tablet?
Q. Tablet, yes.
A. I only use lubricant most of the time when I make a tablet.
Q. The second thing you said when you were giving that long definition of lubricant was that: The lubricants are shown in the Handbook of Pharmaceutical Excipient, they have specific lubricant section --
A. Yes.
Q. -- is that right?

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A. Yes.
Q. If something is not in the pharmaceutical -- sorry.
If something is not in the HPE as a lubricant, does that mean it's not a lubricant?
MR. JAGOE: Objection to form.
A. Not sure what we are talking about.
Can you give me a specific example?
Q. Sure.
* * *
(Exhibit Park 4, Multipage document entitled: Handbook of Pharmaceutical Excipients, Sixth edition: Colloidal Silicon Dioxide (no Bates Nos.), marked for identification)
* * *
MR. CALVOSA: Handed you what I've just marked Park 4.
I'll represent to you this is an excerpt from the Handbook of Pharmaceutical Excipients we have been talking about, Sixth edition, for -- and correct me if I'm wrong -- colloidal silicon dioxide.
BY MR. CALVOSA:
Q. Is that how you say it?
A. Yes.

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Q. And I'm looking at page 185 of Park 4?
A. Yes.
Q. Bottom bolded, again: 6: Functional Category.
It lists several functions here.
Is that right?
A. Yes.
Q. It does not list lubricant as one of the functions for colloidal silicon dioxide, right?
A. That's right.
Q. Would a POSA then understand that colloidal silicon dioxide is not a lubricant?
A. Well, a POSA would understand colloidal silicone dioxide probably not used as a lubricant as function.
(Pause)
Q. Have you ever referred to colloidal silicon dioxide as a lubricant?
A. I don't think I have.
Q. Do you consider colloidal silicon dioxide to be a lubricant?
A. No. I considered usually as a glidant or glidant -- however you say it.
(Pause)

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Q. You can put that aside for now.
(Pause)
Q. You also said in the answer that a lubricant is a specific class of excipients and they are usually hydrophobic.
Is that right?
A. Yes.
Q. Are any lubricants hydrophilic?
A. Sometimes.
Q. What are some examples of hydrophilic lubricants?
A. I think one of them may be polyethylene glycol, sometimes called polyethylene oxide.
Q. Any others you can think of?
A. Not that I can think of now.
(Pause)
Q. Polyethylene glycol -- that's what you just said -- right? -- polyethylene glycol?
A. Yes.
Q. So a POSA would understand that polyethylene glycol -- the formulation POSA would understand that polyethylene glycol is a lubricant, right?
A. Not -- that's not what I said.

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You asked me whether there are hydrophilic lubricants. I remember for a specific formulation I once tried to use polyethylene oxide as a lubricant.
So -- but polyethylene oxide or polyethylene glycol are usually used for some other functions.
Q. But in that specific example you are talking about, it was a lubricant because you were trying to use it as a lubricant?
A. That's right. You have to specify you use it as a lubricant.
Q. Polyethylene glycol is also a binder, right?
A. If you have a Handbook of Pharmaceutical Excipient, you may find the information there, too.
But one can -- one may be able to use it as a binder.
Q. Have you ever used polyethylene glycol in the same formulation as both a binder and a lubricant?
A. No, I don't think that's possible. No, I have not.
Q. Why is that not possible?

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A. Binder is used to make things bind together, so its function as a lubricant may be very different in that particular formulation.

So I don't think -- I personally have not used one excipient for two different functions.

(Pause)

Q. You have never used one excipient for two different functions in any formulation you have made?

(Pause)

A. You mean in the same formulation?

Q. In the same formulation, yes.

A. I don't think so.

Q. Is it your opinion that a formulation POSA would not use one excipient for two different functions in the same formulation?

A. No, I don't think so. I don't think one excipient can be used two different functions in the same formulation.

Q. And it's your opinion that the formulation POSA would have that same understanding, right?

A. At least that is what I have been teaching and that is what I have been

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practicing.

Q. Okay.

(Pause)

Q. Would a formulation POSA understand that a lubricant is used to reduce the extent of friction between the ingredients in the formulation and the machinery?

A. I'm sorry. In the middle was not clear. I'm sorry.

Q. Sure.

Would a formulation POSA understand that a lubricant is used to reduce the extent of friction between the --

A. Used to --

Q. Sorry. I'll ask it again.

Would a formulation POSA understand that a lubricant is used to reduce the extent of friction between the ingredients in the formulation and the machinery used to make the formulation?

A. Yeah -- I think that's the function of lubricant, to reduce the friction between tablet and tool -- tooling machine.

Q. Would a formulation POSA have the same understanding if it was a capsule formulation as

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opposed to a tablet?

A. I think capsule formulation sometime you may not even need the lubricant. But sometimes you may need the lubricant if you compact the powder into a certain tablet shape. So depending on formulation, especially capsule, you may not even need a lubricant.

(Pause)

Q. Okay.

(Pause)

Q. Would a formulation POSA understand that a lubricant prevents sticking?

A. Sticking between?

Q. The -- in a tablet formulation between the ingredients in the formulation and the machinery used to make the formulation?

A. Well, that's what we talked about before, yes.

Q. Okay.

So sticking is another way -- prevent sticking is another way to say "reduce the extent of friction"?

MR. JAGOE: Objection to form.

A. Extent friction is a different thing. Adhesion, friction, maybe the

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lubricant is used to reduce the sticking between tablet and tooling machine, so that when you eject tablet you have an intact form of tablets.

Q. Okay.

Would a formulation POSA understand that a lubricant is a slippery solid?

(Pause)

A. I'm not sure what that means, but -- I cannot say, no.

What is slippery solid?

Q. I don't know. I was reading one of your patents.

MR. CALVOSA: Let's take a look at that.

* * *

(Exhibit Park 5, Multipage document entitled: United States Patent No.: US 6,960,617 B2, dated November 1, 2005 (no Bates Nos.), marked for identification)

* * *

MR. CALVOSA: I've marked for the record Park 5. This is U.S. Patent No. 6,960,617 B2.

THE WITNESS: Yes.

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BY MR. CALVOSA:
Q. And there is a -- in the inventor's section up here -- by the (75) in parenthesis -- there is listed Kinam Park, West Lafayette Indiana, and then (US) in parenthesis.
Is that you?
A. I hope so.
Q. Don't know other Kinam Parks in here?
A. This is me, yeah.
Q. You are listed as an inventor on this patent, right?
A. Yes.
Q. Are you familiar with this patent?
A. Yes, I am, but it was a while ago, but I remember it, yes.
Q. I'm looking in column 31 about line 27?
A. Yes.
Q. You see there it says: A lubricant is necessary.
And it goes on?
A. Yes.
Q. The second sentence, you said: The lubricant is chosen from such slippery solids as talc, magnesium and calcium stearate, stearic

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acid and hydrogenated vegetable oils.
Do you see that?
A. Yes.
Q. That's why I asked you if a formulation POSA would understand that a lubricant is a slippery solid?
(Pause)
A. Yes.
It said: Slippery solids such as a talc, magnesium and calcium stearate, stearic acid, and hydrogenated vegetable oils, yes.
Q. So are -- would a formulation POSA understand that lubricants are always slippery solids?
(Pause)
A. In the beginning when you receive the material, they are solid. But you use a certain small quantity of it to use it as a lubricant.
(Pause)
Q. I was focused more on the "slippery," but that's okay.
Are lubricant -- would a formulation POSA understand that lubricants are always slippery, whether they are solids or in another form?

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A. I don't think that's how you read that.
They are simply saying: Lubricant such as talc, magnesium, calcium stearate, stearic acid are slippery solid.
That does not mean all slippery solid -- whatever they are -- are lubricants.
Q. Does that mean that all -- let me ask it another way.
Could you have a lubricant that is not a slippery solid?
(Pause)
A. I cannot think of now.
But slippery solids like a Teflon, is slippery solid, but it cannot be used as a lubricant.
Q. My question was: Can you have a lubricant that is not a slippery solid?
A. Again, I cannot think of right now.
(Pause)
Q. Okay.
You mentioned in that list manganese stearate.
Is magnesium stearate -- or would a formulation POSA understand that magnesium

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stearate is a lubricant?
A. Yes.
Q. What if a formulation was made up of 50% active ingredient and 50% magnesium stearate?
Would the magnesium stearate still be a lubricant?
MR. JAGOE: Objection to form, incomplete hypothetical.
A. First of all, I'm not sure why anybody want to make such a formulation.
And I don't think that that's a reasonable formulation in this right now, without any specific goals you can tell me.
Q. I agree it's not a reasonable formulation. I think I know why.
Is it because there is too much magnesium stearate in the formulation at that point?
MR. JAGOE: Objection to form.
A. Again, this is hypothetical. Unless you give me specific example and why you make it for the goal you have, then I can tell you. But otherwise, it's just too hypothetical.
Q. Is there a concern that's well known

to formulation POSAs about adding too much magnesium stearate to a formulation?
A. Yes. That is known. Because if you add too much magnesium stearate -- for example, more than 1%, 2% -- then whole tablet may become too hydrophobic, so they may not resorb in water. So tablet may not even disintegrate.
(Pause)
Q. Earlier you said -- and please correct me if I'm wrong -- that a capsule formulation you may not need a lubricant.
Is that right?
A. Yes.
Q. Why in your opinion is that the case?
A. Sometimes capsule filling is such that in pouring in the powders and swipe them to fill the underneath capsule -- half of the capsule -- as long as powder flows well, you don't need a lubricant.
Q. Can you turn to Park 2, paragraph 22, which spans from page 7 to 8?
(Pause)
A. Yes.
Q. I just want to confirm that the -- that -- I guess, the sentence beginning on the

very last line of page 7 that begins with "A" through the remainder of the paragraph -- that's still your opinion?
(Pause)
A. Yes.
Q. If you could turn back to Park 3, that was one of the earlier portions of the HPE I gave you on dextrose.
A. Yes.
Q. Again I want to focus on page 222, the: Functional Category.
A. Yes.
Q. At the beginning, it says that dextrose can be a tablet and capsule diluent?
A. Yes.
Q. And I believe before you said that "diluent" and "filler" are often used interchangeably?
A. Yes.
Q. And a formulation POSA would understand that, right?
A. Yes.
(Pause)
Q. In what situation could a -- could dextrose be used as a tablet diluent but not a

sweetening agent?
MR. JAGOE: Objection.
A. You asked me: What situation?
Q. Yes.
A. Well, again, if tablet or capsule is designed to swallow, you don't need any sweetening function.
But in my case, I made a formulation that dissolve in the mouth, so I use it as a sweetening agent.
Q. Okay.
In what situation could dextrose be used as a diluent in a dissolvable tablet, but not a sweetening agent?
A. If you -- the goal of a formulation scientist to bulk up the total amount because drug amount is so small, then you use glucose as a diluent. That's the main function of glucose, specifically used as a diluent.
(Pause)
Q. So the function of the excipient is based on the formulator's goal?
A. Absolutely.
(Pause)
MR. CALVOSA: Want to take a quick

break? Is that okay with you?
MR. JAGOE: Yeah.
THE VIDEOGRAPHER: The time now 11:44 a.m. and we are off the record.
* * *
L U N C H R E C E S S
* * *

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* * *
AFTERNOON SESSION
* * *
* * *

(Exhibit Park 6, Multipage document bearing heading on first page: Exhibit 1, entitled: Curriculum Vita: Kinam Park, dated November, 2018 (no Bates Nos.), marked for identification)

* * *

THE VIDEOGRAPHER: This marks the beginning of tape No. 3. The time now is 12:32 p.m. and we are back on the record.

BY MR. CALVOSA:

Q. Welcome back from lunch, Dr. Park.

A. Thank you.

MR. CALVOSA: I'm handing you what is marked as Park 6. And Park 6 was also Exhibit 1 to your original declaration, which is Park 1.

BY MR. CALVOSA:

Q. Do you recognize Park 6, Dr. Park?

A. It is my CV.

Q. If you turn to the first page, there is no page number on that one.

But at the top it's indicating -- or

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at least it states the date of November, 2018?

A. Yes.

Q. So can I take that to mean that this CV was current as of November, 2018?

A. Yes.

Q. Has there been any significant additions that you would like to add here now?

A. No, other than some more publications.

Q. No new academic appointments on page 1?

A. No.

Q. What about any new degrees for education?

A. No.

Q. If you turn to page 5 of Park 6, there is a section entitled: Books.

Do you see that?

A. Yes.

Q. There is 12 books listed. I would like you to look at the one with the No. 9 in front of it.

A. Yes.

Q. How do you pronounce the other author's name?

A. Wen.

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Q. That's a book entitled: Oral Controlled Release Formulation Design and Drug Delivery: Theory to Practice?

A. Yes.

Q. And that was edited by yourself and Dr. Wen?

A. Yes.

Q. Is that book something a formulator would consider?

A. I sincerely hope so.

Q. Does that book, in your opinion, provide reliable information?

A. Yes, I think so.

(Pause)

Q. Dr. Park, you do not hold a medical degree, correct?

A. That's correct.

Q. And you are not a medical doctor, right?

A. Right.

Q. You are not licensed to prescribe pharmaceuticals, right?

A. Right.

Q. And you do not administer pharmaceuticals to -- other than yourself --

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patients, right?

A. Right.

Q. Do you consider yourself a specialist in oncology?

A. I'm not sure what you mean by "specialist" in that particular case. But I have been studying formulation on cancer drug delivery systems.

Q. That's fair.

Do you consider yourself an expert in the field of treating cancerous conditions?

A. In the sense that developing a formulation for treating cancer, I am expert; but not treating with dealing with a patient themselves.

Q. Have you ever developed a pharmaceutical for the treatment of multiple myeloma?

A. Not that particular cancer.

But I have made several formulations to treat cancers --

Q. Okay --

A. -- in general.

Q. Sorry for interrupting you.

Nothing -- you have not developed any

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formulation for the treatment of multiple myeloma specifically.
Is that fair?
(Pause)
A. Depending on the clinician, they may use a certain drug that I used. So I'm not sure whether I can say exclusively that it was not related.
Q. To your knowledge, no drug product you have developed has been used for the treatment of multiple myeloma?
A. No.
Q. By "no," you are agreeing that I was correct, right?
A. Yes.
Q. What is multiple myeloma?
MR. JAGOE: That's outside the scope of the declaration.
So you can answer, but not on behalf of defendants.
A. One of the cancers.
Q. Okay.
But how do you tell if a patient has multiple myeloma?
A. Did I say anything about that in my

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report?
Q. I'm just asking if you know. We can look at your report in a second. We will. And we'll go to your report.
I'm just asking if you can tell if a patient has multiple myeloma?
A. Do I know how a patient has multiple myeloma?
Q. Do you know how to tell if a patient has multiple myeloma?
A. I guess one has to do some lab test.
Q. Okay.
MR. CALVOSA: And just to be clear, he is -- this witness -- all of his answers are on behalf of Teva.
MR. JAGOE: No.
MR. CALVOSA: You could object as outside the scope, but all of his answers are on behalf of Teva -- and I understand Mylan and everybody, except Apotex and possibly Breckenridge as well.
MR. JAGOE: Well, I disagree. And since you explained your position I'll explain mine.
MR. CALVOSA: Go on.

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MR. JAGOE: He's answering for Teva for the scope of his declaration in the Markman proceeding.
And to the extent you ask him questions outside of that, it's not on behalf of Teva.
And I drew a line for that last question to tell you.
* * *
(Exhibit Park 7, Multipage document bearing heading on first page: Exhibit 1, entitled: United States Patent No.: US 8,198,262 B2, dated June 12, 2012 (no Bates Nos.), marked for identification)
* * *
MR. CALVOSA: I have marked as Park 7 what is U.S. Patent 8,198,262.
THE WITNESS: Yes.
MR. CALVOSA: And it is also attached as Exhibit 1 to my declaration of the open claim construction brief.
BY MR. CALVOSA:
Q. Feel free to look at your report, but this is one of the patents that you opined.
Is that right?

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A. Yes.
Q. Did you read this patent?
A. Yes.
Q. Did you understand everything in the patent when you read it?
A. I understand to the extent that I wrote the report.
Q. So there are some portions of this patent that you understand; some portions that you don't understand.
Is that fair?
A. No, I didn't say I did not understand.
I just read the portions relevant to my report.
Q. Didn't you want to read the entire patent before writing your report?
A. "Entire" means word-by-word from very beginning until the end?
Q. Yes.
A. I read most of the text and claims. But I don't think I read all these references, word-by-word.
Q. Okay. So let's start on column 1.
Did you read from column 1 through the claims in its entirety?

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A. That's most of it.
Q. So the answer is no, then, right?
A. That's not what I said. Again, I didn't say -- I didn't read word-by-word, but I read most of it.
Q. Okay.
And you understood everything you read.
Is that right?
A. Yes.
(Pause)
Q. Can you look at column 4?
A. Yes.
Q. About line 21, it says: Brief Description of the Figure?
A. Yes.
Q. Did you read that from lines 21 through line 30 -- the brief description of the figure?
(Pause)
A. Yes.
Q. And you understood that?
(Pause)
A. Yes.
Q. Can you explain to me what the Hs

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Sultan MM cell line is?
MR. JAGOE: Outside the scope, objection.
(Pause)
A. I think this is one of the -- our cancer cell lines.
Q. What do you mean -- "our cancer cell lines"?
MR. JAGOE: That's not what he said.
BY MR. CALVOSA:
Q. It says: I think it's one of our cancer cell lines.
I asked: What do you mean -- "our cancer cell lines"?
A. One of the cancer cell lines.
Q. Ah.
And what are the cancer cell lines?
A. So you are asking me general questions?
Q. Yes.
A. What are not in my reports?
Q. I'm following up.
You said you read this patent, you understood it.
A. There are many cancer cells available

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for testing different drugs.
Q. How many?
MR. JAGOE: Outside the scope.
A. Again, I don't know how many exactly there are.
Q. When you say "many," what do you mean?
A. "Many" means plural. There are more than a dozen. Exactly I don't know how many, but it's not one.
Q. Did you say "dozen" or "thousand"?
I'm sorry. I didn't hear you.
A. I don't know the exact number.
I said: More than a dozen. That's many.
Q. But you are certain that the Hs Sultan cell line is an MM cell line?
MR. JAGOE: Objection to form.
A. That's what it says here: MM cell lines, Sultan. So I have no reason not to believe it.
Q. Would a formulation POSA understand that the Hs Sultan is an MM cell line?
A. Formulation scientist will focus on formulation, not particular cell lines.
Also, this is not what I mentioned in

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my report.
Q. Well, you said you read it all and you understand it. And you are offering an opinion on it, so I'm trying to understand --
MR. JAGOE: He's not offering an opinion on cell lines.
MR. CALVOSA: He's offering an opinion on the patent.
You got to read the whole specification, don't you?
You have been educating me on the law all day.
MR. JAGOE: You want to talk about it, or not?
MR. CALVOSA: Yeah, okay.
MR. JAGOE: Okay. Let's talk about it.
He's offering an opinion about what's in his two declarations. He cited parts of the patent that he's relying on in his declaration, and that's what he's relying on.
And this is not cited in his declaration, and he's not being called as an expert on multiple myeloma cell lines.
MR. CALVOSA: So it's your position

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that he did not consider the patent in whole?
MR. JAGOE: I didn't say that.
I said what he's relying on --
MR. CALVOSA: Is it your position that he considered the patent in whole?
MR. JAGOE: You have his testimony. He said he did.
I don't have to take a position on a fact.
MR. CALVOSA: Yes, you guys are funny. All right.
BY MR. CALVOSA:
Q. What were the -- and we'll get back to the cell lines in just a second.
(Pause)
Q. What type of problems were encountered in the art for multiple myeloma in 2002?
A. I come here today to talk about my reports. That was not in my report.
Q. Okay. Fair enough.
And it's not in your report or -- let me ask you another question.
Have you considered in forming the opinions in your report what type of problems were encountered in the art for multiple myeloma

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in 2002?
(Pause)
A. What type of problems were there 2002?
I was only considering that claim construction of about 1 milligram to about 5 milligram, etc. So that's what I'm here to testify.
Q. Let's look at paragraph 18 of Park 1.
(Pause)
Q. It talks about the method of treatment patents.
Do you see that?
A. Yes.
Q. You understand the '262 patent is one of the method of treatment patents, right?
A. Yes.
Q. How did you come up with your person of ordinary skill for the method of treatment patents?
MR. JAGOE: Don't disclose any conversations with counsel -- the substance of any conversations with counsel.
A. Method of treatment requires development of a formulation that clinicians can use.

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So in this case, person of ordinary skill in the art may include formulation scientists as well as clinicians, and they may work as a team.
Q. Okay.
How did you come up with the idea that the clinician or medical oncologist would need several years of experience in cancer research, for example?
A. To really build up expertise in medical oncology, after finishing medical school, you need to go through intern resident and build up the expertise. So I thought that several years would be a proper time period.
Q. How many years is "several"?
A. When I mean several, it is like five to six, or around that number.
Q. Okay.
What do you mean by "cancer research" when you say that?
A. Cancer research include understanding why cancer is caused, or what kind of drug can be used, or depending on cancer type, which drug may be useful. Depending on patient, some drug may be beneficial more than others, etc.

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Q. Okay.
How is it determined whether a drug can be used for the cancer type?
A. Depending on the type of cancer, there are certain drugs known to be useful, but same drug may not work for all patients. So you have to choose the right drug for the right patient.
Q. Will the same drug work for all types of cancer?
MR. JAGOE: Objection to form, outside the scope.
A. Again, that's not in my report. But you may be asking general questions.
And the question was whether one drug works for all types of cancer?
Q. That's right, yeah.
A. I don't think so.
Q. And when you mean "cancer research," do you mean "laboratory work"?
A. No, it can be a laboratory as well as a clinical settings.
Q. What type of clinical settings are you thinking of?
A. You need to try a certain drug in the cancer patient and see whether it works or not.

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Sometimes there is clinical trials.
(Pause)
Q. So to see whether the cancer drug works, you need to try it in the patient and see whether it works or not?
A. Yes.
(Pause)
Q. Can you turn to page 10 of Park 1?
(Pause)
Q. And you talk here -- and it goes on to page, I guess the top of page 13 -- about the '427 patent file history?
A. Yes.
Q. Did you review the entire '427 file history?
A. Again, I'm not sure what you mean "entire."
But I did not read the -- word-by-word the whole patent history.
Q. Did you have the entire '427 patent file history available to you?
Or were you given just certain portions of it for your review?
A. No, I had the entire file history.
Q. I'd like you to look at paragraph 32.

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(Pause)
A. Yes?
Q. In that last sentence, you say: For example, the pomalidomide could be less than 100% pure or be in salt form, as long as the amount of pomalidomide compound is equivalent to [x] mgs of 100% percent pomalidomide.
Do you see that?
(Pause)
A. Yes.
Q. What do you mean when you say: Less than 100% pure?
A. As I said here in this paragraph, if pomalidomide is in a salt form, the weight of salt is added, so pomalidomide will not be 100% pure.
Q. So when you say "less than 100% pure," you mean if a salt is present?
A. Salt or solvate -- solvent molecules. If there are other molecule is present, pomalidomide will not be 100% pure.
Q. What do you mean by: Other molecules present?
A. Salt or solvate molecules.
Q. Anything else?

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(Pause)
A. Monohydrate belongs to solvate, too -- so anything other than pomalidomide.
Q. What about residual solvents?
MR. JAGOE: Objection to form.
A. Residual solvents of solvate form?
Or what?
Q. Sure, of solvate form.
MR. JAGOE: Objection to form.
A. So question is whether solvate solvent remains as a residuals in the drug?
Q. Yeah.
A. If it exists as impurities, then you may have to clean up or remove it.
But at least in the patents I opined on it, I was looking into salt form solvate, two forms.
Q. So let me ask it another way.
If I have impurities, as you put it, in my pomalidomide, is that 100% pure pomalidomide?
MR. JAGOE: Objection to form.
(Pause)
A. I think 100% pomalidomide is pomalidomide in base form.

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So when we talk about salt or solvate, you have more than pomalidomide base. I think that's what we are talking about. So 100% pure means pomalidomide base.
Q. So 100% pure pomalidomide, as long as it's the base, can include impurities?
MR. JAGOE: Objection to form.
Q. Minus the solvates and the salts, right?
A. I'm not sure -- I don't know that that's what I opined on it, but I'm not sure your question has specific information.
So what kind of a solvate? What kind of solvate impurity is how you make it.
I don't know. Again, that's not what I opine in my report. So --
Q. Okay.
So you don't have an opinion one way or another whether, if I have an impurity in the pomalidomide free base, that's 100% pure pomalidomide?
A. Until I have more information and more time, at this point, I don't have an opinion.
Q. Okay.
(Pause)

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Q. When you say pomalidomide free base and we could use the pomalidomide salt as the other one, and I think you used specifically pomalidomide hydrochloride as an example in your declaration -- let's go look at that. That might be easier.
(Pause)
Q. I'm looking at paragraph 43 of Park 1.
(Pause)
A. Yes.
Q. And here you are saying that the molecular weight of the pomalidomide salt is greater than the pomalidomide free base, right?
A. Right.
Q. And that makes sense -- right? -- because there is a -- now the -- the counterion has joined the molecule, if you will.
Is that accurate?
A. Pomalidomide salt is -- molecular weight-wise -- higher than pomalidomide base because of presence of salt.
Q. If I have pomalidomide, is it possible to have a mixture of the pomalidomide base and the pomalidomide salt?
Or is it just one or the other?

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MR. JAGOE: Objection to form.
(Pause)
A. Well, it depends on condition. But when you make a salt, you will probably make all the salt form.
Q. And if I have a pomalidomide hydrate, again, is it possible to have a portion that's a free base and a portion that's a hydrate?
Or is it 100% of the pomalidomide hydrate?
A. In a salt form, depending on pH and other conditions, you -- it's not equilibrium.
But in hydrate, condition may be such that you may have a hydrate form.
Q. So I may have.
And correct me if I'm wrong.
You mentioned equilibrium. So for the hydrate, I may have portion of the pomalidomide that's in the hydrate form and a portion that's in the free base form.
Is that what you are saying?
MR. JAGOE: I object to the extent you are trying to use this proceeding to get evidence for another proceeding.
MR. CALVOSA: Trying to get it for

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claim construction.
MR. JAGOE: I think you are trying to get it for the other case you filed.
MR. CALVOSA: Trying to get it for claim construction --
MR. JAGOE: I think you're not --
MR. CALVOSA: -- talks about hydrates.
MR. JAGOE: -- that's my objection.
If you want to debate it, we can. I just made an objection.
MR. CALVOSA: Okay, go ahead.
MR. JAGOE: Try to use it in the other case, I'll bring it up to the judge that I objected to it.
MR. CALVOSA: Okay.
You have no objection to us using it in the claim construction proceeding, correct?
MR. JAGOE: If you think it's somehow relevant. I don't see why it's relevant in this claim construction proceeding.
But -- I mean, I don't know how much you want me to say, but I made my objection.
MR. CALVOSA: Okay. Back to the question.

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BY MR. CALVOSA:
Q. And correct me if I am wrong -- you mentioned equilibrium in the previous answer when you were talking about the salts and the hydrate.
The way I understood what you were saying was that it's possible, because of the equilibrium, to have some of pomalidomide in the hydrate form and some of the pomalidomide in the free base form?
A. I didn't say for hydrate. That was for salt form, which is a function of pH.
But, again, my report does not contain it, so I would not opine on that particular point.
Q. You have no opinion one way or another whether the pomalidomide -- if it's with the hydrate -- can be partially with the hydrate and partially free base, versus 100% on the hydrate?
A. I have no opinion on that.
Q. And you have no opinion whether, if the pomalidomide is with the salt, it could be a portion of the pomalidomide salt and a portion in the free base?
Or 100% of the pomalidomide salt?

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A. At this point, I have no opinion.
Q. And you have on neither of those offered any opinions in your declarations, right?
A. That's what I said. I did not present any opinion on that.
Q. Okay.
* * *
(Exhibit Park 8, Document Bates stamped DEFS_POM_00013788 through 13797, multipage document bearing heading on first page: Exhibit 7, entitled: Pharmaceutical Calculations, 13th Edition, marked for identification)
* * *
MR. CALVOSA: I have just marked as Park 8 what was Exhibit 7 to Dr. Park's original declaration, which is Park 1.
THE WITNESS: Yes.
BY MR. CALVOSA:
Q. Do you recognize what I have marked as Park 8?
A. Yes.
Q. What is it?
(Pause)

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A. It is Ansel book on pharmaceutical calculations.
(Pause)
Q. I believe you refer to this Park 8 in Park 1 as "2010 Ansel." And I'm looking on page 26 of Park 1, the very bottom.
A. Yes.
Q. Is it okay if I call Park 8 "Ansel 2010"?
A. Yes.
Q. "2010 Ansel."
Would the formulation POSA have been aware of Ansel's 2010?
A. Yes.
Q. What about the POSA for the method of treatment patents that you talk about in paragraph 18 of Park 1?
Would that method POSA have been aware of Ansel 2010?
A. They would, as I said, work with the other formulation expert team, so they may have informed them.
Also, this calculation is really straightforward arithmetic calculation.
(Pause)

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Q. Would you say that the calculations in Ansel 2010 are well-known calculations in the pharmaceutical industry?
A. In terms of calculating amount of active ingredients in salt form or solvate, any person who has education like a POSA would understand.
(Pause)
Q. Do you understand whether the POSA is supposed to be evaluated -- claim construction -- at the time the claim invention was made -- for example, the priority date?
A. Yes, that's what I did.
Q. Okay.
I would like to look on Ansel 2010, page 327?
A. Sorry?
Q. Ansel 2010 at page 327.
A. Ansel -- I'm sorry, what page?
Q. Sure, 327.
A. 327. Yes.
Q. I'm going to ask these questions for both of your POSAs -- the method POSA and the formulation POSA.
And if it's the -- I'll consider, you

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know, if the method POSA would have been informed by the formulation POSA, that's fine as well. But I'm asking whether each of them would have known this.
A. Each of them what?
Q. Each of the POSAs would have known this.
So the section heading is: Active Drug Moiety Equivalents?
A. Yes.
Q. Would both of your POSAs have known that in pharmacotherapeutics, it is the pharmacologically active moiety of a drug compound that is responsible for the therapeutic response?
A. That's what it says.
The question is?
Q. Would both of your POSAs been aware of that?
A. Oh, I think so.
Q. Would both of your POSAs have been aware of that to accommodate such diverse factors such as -- sorry.
Let me start again so I don't mess it up.

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Would both of your POSAs have been aware of that -- to accommodate such diverse factors as drug solubility, drug absorption, and formulation/dosage form considerations, an active drug moiety may be developed into a salt, ester, or other complex chemical form?
A. So the question is: Those POSA would understand?
Q. Would both of your POSAs have been aware of that?
A. I think so.
Q. In the '262 patent and in all the method of treatment patents, the active moiety is pomalidomide, right?
(Pause)
A. Yes, pomalidomide, yes.
Q. And specifically, the free base of pomalidomide, right?
A. Yes.
Q. I would like to turn to page 325 of the same exhibit.
(Pause)
Q. I'm looking under the section heading: Objectives.
A. Yes.

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Q. Would both of your POSAs have been aware that: A pharmacist must be able to calculate the pharmacologically active drug and -- in parenthesis -- (chemical) moiety when present in salt, ester, hydrated, or complex chemical form?
A. Yes.
Q. Would both of your POSAs have been aware that: Such calculations are essential when quantitively comparing products of the same drug moiety but differing in chemical form?
(Pause)
A. Yes.
Q. Would your -- both of your POSAs have been aware that: These calculations are applied in compounding procedures in which a different form of a drug is used to satisfy formulation requirements while the quantity of the pharmacologically active drug moiety is maintained at the desired therapeutic dose or concentration?
(Pause)
A. The question is whether both POSAs would understand that?
Q. Would both of the POSAs have been

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aware of that? -- yes.
A. Well, I think so. Certainly formulation scientist will understand this.
Q. Under your definition of the method POSA, they would be informed by the formulation scientist, right?
A. I think so, yes.
* * *
(Exhibit Park 9, Multipage document bearing heading on first page: Exhibit 8, entitled: Pharmaceutical Calculations, 11th Edition: 17: Calculation of Active Drug Moiety (no Bates Nos.), marked for identification)
* * *
MR. CALVOSA: Marked as Park 9 what is Exhibit 8 to Dr. Park's original declaration, which is Park 1.
THE WITNESS: This is 11th edition?
MR. CALVOSA: I'm sorry?
THE WITNESS: This is 11th edition of Pharmaceutical Calculations?
MR. CALVOSA: Are you asking me? Or telling me?
THE WITNESS: No, no. It said 11th Edition Pharmaceutical Calculations.

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Yes, this is what you gave me.
MR. CALVOSA: Yes.
BY MR. CALVOSA:
Q. And do you recognize Park 9?
A. Yes, but I'm trying to figure out why there is -- my report is 13th edition.
(Pause)
Q. I think if you turn the page to page 27, this was Exhibit 8 to your report.
Or at least trying to confirm that it was, and that is the 11th edition?
A. Okay. So I was -- yeah, you are right, okay. This is what it is, yes.
Q. This is 2001 Ansel, right?
A. Yes.
Q. It's your opinion that both of your POSAs would have been aware of 2001 Ansel, right?
A. Certainly formulation scientist will understand this particular book.
Q. And the formulation scientist in your opinion would have informed the method POSA, right?
A. If I asked, yes.
Q. What do you mean: If I asked?

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A. No, no, if were asked --
Q. Okay. Sorry.
I'm happy to go through the quotes with you, but maybe it's better if you just review your report here.
The information that's in Ansel 2001 that I've marked as Park 9 is either verbatim or almost verbatim as the information in Park 8, right?
(Pause)
A. So what is your question?
Q. I read Park 8 -- sorry.
I read Park 9.
And it seemed to provide the same information that was in --
A. Which portion --
Q. -- Park 8 --
A. -- did you read?
Q. The whole thing.
Did you not?
A. No, no, you said you read this one. You read the portion of Park 9.
So which portion did you read?
I may have misunderstood your question.

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Q. Okay. Let's just ask the questions --
A. Okay.
Q. -- it's easier.
(Pause)
Q. I'm looking at page 255 of Park 9.
A. Yes.
Q. And specifically the section that says: Active Drug Moiety Equivalence?
A. Yes.
Q. If you look at Park 8, that same section on page 327, the first two paragraphs, does that provide the same information?
A. Yes.
Q. And if you look at Park 9 on page 253 and Park 8 on page 325 -- the first paragraph on page 253 of Park 9 -- does that provide the same information as the paragraph that begins "A pharmacist must" on page 325 of Park 8?
(Pause)
A. Yeah.
Q. If we go to Park 8, page 328, I'm looking at the: Example Calculations of Active Drug Moiety Equivalence?
A. Yes.
Q. And I'm specifically looking at the

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third example there about lidocaine?
A. The last paragraph?
Q. The last -- the last one there, yeah, at the bottom of the page.
A. Yes.
Q. And here, when they want to use a solution of 300 mgs lidocaine to prepare that solution -- or I guess an equivalent of that solution would be 369 milligrams of lidocaine hydroxide, or -- let me ask the question again.
In this example, it shows that, if the desired dose is 300 mgs of lidocaine, and if the pharmacist chooses to use lidocaine hydrochloride to prepare that 300 mg dose, they have to use 369 mgs of lidocaine hydrochloride. Right?
A. That's the calculation.
Q. And why is that calculation done?
(Pause)
A. Because it was a lidocaine salt form.
(Pause)
Q. And they wanted to keep the amount of the active moiety constant, right?
MR. JAGOE: Objection to form.
A. I'm not sure constant, but the desired

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amount.
Q. Okay.
They wanted to achieve the desired amount of 300 mgs of the lidocaine active moiety, right?
A. Yes.
Q. And to do that, you have to use more of the lidocaine hydrochloride, because it's in the salt form, right?
A. Yeah, you need a higher amount because a salt weight is added, yes.
(Pause)
MR. JAGOE: Do you need a break, Doctor?
THE WITNESS: Yeah.
THE VIDEOGRAPHER: The time now is 1:32 p.m. and we are off the record.
(Recess from 1:32 p.m. to 1:49 p.m.)
THE VIDEOGRAPHER: This starts the beginning of tape No. 4. The time now is 1:49 p.m. We are back on the record.
BY MR. CALVOSA:
Q. Welcome back, Dr. Park.
A. Thank you.
(Pause)

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MR. CALVOSA: I'm going to hand another exhibit.
(Pause)
MR. CALVOSA: Exhibit 9 -- that one is marked Park 10, but Exhibit 9 to your opening declaration, which was Park 1.
* * *
(Exhibit Park 10, Document Bates stamped DEFS_POM_00013803 through 13816, multipage document bearing heading on first page: Exhibit 9, entitled: The United States Pharmacopeia: The National Formulary, dated May 1, 2008, marked for identification)
* * *
MR. CALVOSA: It says "Exhibit 9" on the front, but it was marked Park 10 for this deposition.
THE WITNESS: Yeah.
(Pause)
BY MR. CALVOSA:
Q. I would like you to turn to page -- well, I guess, first of all, do you recognize what this is?
A. Yeah, USP National Formulary 2008 edition.

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Q. You cited this as one of the exhibits to your opening declaration -- Park 1 -- right?
A. I think so.
Q. Would both of your POSAs have been aware of this USP?
A. Yes, in particular, formulation POSA.
Q. Maybe that's something we need clarification on.
You said the formulation POSA could assist the method POSA, right?
A. Well, as I said, a POSA could be a team of scientists. So clinicians and formulation scientists can be collectively a POSA here.
Q. For your definitions of the POSA, though, the formulation POSA is the one doing the formulation of the drug product, right?
A. Yes, making formulations, yes.
Q. And then the method POSA is the one who is giving the drug product to the patient, right?
A. Using the formulation to treat the patients, yes.
Q. So they -- the method POSA does not make the formulation themself, right?

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MR. JAGOE: Objection to form.
A. I cannot tell in general.
But usually, formulation scientists develop formulation, but clinicians sometimes develop formulation, too.
Q. Under your definition of the method POSA, are they a formulator or a clinician?
A. For method treatment?
Q. Yes.
A. Again, as I said, this is a combination of different expertise including clinicians and formulation scientists.
(Pause)
Q. By the time the clinician gives the pill to the patient, the pill is already made, right?
MR. JAGOE: Objection to form.
A. Are you talking about clinical settings?
Or can you be a little more specific?
Q. Sure, clinical setting.
A. So clinician is giving a pill to a patient, then the formulation is already made and approved by the FDA.
Q. Okay.

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A. I think you are not talking about clinical trials where you don't need to have an approval or in any experimental settings.
Q. I don't know if I would put that qualification on.
Just what I'm trying to understand is: By the time you get to the point where the patient is putting the pill in his or her mouth, the formulation has already been made.
A. Again, I cannot tell in general because formulation development may occur during the clinical trial. Sometime they can even change after clinical Phase I study, too.
So I cannot tell in general whether what you describe is true or not.
Q. Okay. Would be a little bit more specific then.
By the time the patient is putting the actual pill -- or the specific pill -- in his or her mouth, that pill has already been formulated, right?
A. Once anybody take a pill, you may consider it is a formulated tablet, or capsule, or whatever it is.
(Pause)

Q. Let's look at Park 10.
Would both of your POSAs have been aware of Park 10?
A. Again, USP is usually for formulation scientist. So some clinicians who are interested in developing formulation, they may be looking into USP.
Q. Let's look at page 627 of Park 10.
(Pause)
A. 627? Yes.
Q. I'd like to look at the section that has the heading: Calculations in Compounding?
A. Yes.
Q. And specifically that last paragraph in the left-hand column?
A. Yes.
Q. It says -- and correct me if I'm wrong -- it's talking about situations where a drug substance is either in a salt or complex?
A. Or an ion.
Q. Okay.
And in those situations, it said the drug substance weighed -- a portion of it represents the pharmacologically active moiety.
Is that right?

A. Yes, that is what it describes.
Q. Would your POSA have been aware that when a formulation or -- sorry.
Would your POSA have been aware that when a drug is in a salt or complex, that a portion of that represents the pharmacologically active moiety?
A. I'm sorry. I was not clear about your question. Would you repeat?
Q. Sure. Let's break it down, just so it is simpler.
If we have a drug in a salt form, both of your POSAs would have been aware that a portion of that salt form represents the pharmacologically active moiety.
Is that right?
A. A special formulation POSA would understand that.
Q. Your POSA would have been aware that, if a compound is in a salt form, for example, it must be weighed calculated on the basis of the required quantity of the pharmacologically active moiety, right?
A. I'm not sure whether it must. I don't know -- I don't really know the specific

circumstances you are talking about.
But if instruction said just certain amount which is not clear about exactly what it has -- you know, pure drug active moiety or not, you have to be -- you have to be clear about what you are using, what you need to measure.
Q. I'm reading the last paragraph here and maybe it's easier this way.
Would your POSA disagree with the information provided in the last paragraph here in the left-hand column of page 627?
A. I don't think POSA will disagree.
This is what I said in my report. To calculate the active moiety itself, you have to consider the percent of salt, etc.
(Pause)
MR. JAGOE: This exhibit you gave the witness has handwriting. Is that the one you --
MR. CALVOSA: That's the one I was looking for.
MR. JAGOE: If you want to switch it later or --
(Pause)
MR. CALVOSA: Thank you for that.
BY MR. CALVOSA:

Q. For hydrates -- we just talked about salts -- but it says earlier in this section -- and I'm looking about halfway down the first paragraph --
A. First paragraph?
Q. Yeah.
It says: Calculations must account for the active ingredient, or active, moiety and water content of drug substances, which includes that in the chemical formulas of hydrates.
(Pause)
A. Yeah -- when you calculate amount of active moiety, you, of course, have to consider inactive ingredient.
Q. And this is referring to an active ingredient?
A. What refers to active ingredient?
Sentence?
Q. Maybe I misunderstood you.
The sentence there -- it says: Calculations must account for the active ingredient, or active moiety, and water content of drug substances, which includes that in the chemical formulas of hydrates.
And I'm asking: Would your POSA agree

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with that statement?
A. This POSA will agree, because that's what you need to calculate. That's what I mentioned in my report.
Q. That's what you mention in your report where you say that --
A. That's what I say in my report.
Q. -- that if it's a hydrate, for example, you would need more of the hydrate to get the same amount of the free base?
A. To calculate the amount -- certain amount of active ingredient, you have to calculate the total amount -- hydrate in this case.
Then you have to subtract the amount from total weight.
This is how we calculate amount of active ingredient from salt or hydrate.
Q. So for a salt, you would subtract out the salt portion of it.
Is that right?
A. Again --
Q. I'm trying to understand.
So if you would like to put it in your own words, I'm just trying to understand what

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the opinion is.
MR. JAGOE: Objection to form.
A. So if a person or POSA is asked to calculate exact amount of active ingredient in a salt or hydrate, then they will have to consider the weight of salt or hydrate.
Q. Okay.
* * *
(Exhibit Park 11, Multipage document bearing heading on first page: Exhibit 10, entitled: The United States Pharmacopeia: The National Formulary, dated January 1, 2000, marked for identification)
* * *
MR. CALVOSA: Marked as Park 11 what is Exhibit 10 to Dr. Park's original declaration, which is Park 1.
(Pause)
BY MR. CALVOSA:
Q. Do you recognize this document, Dr. Park?
A. The USP 24, NF 19, publication 2000.
(Pause)
Q. This was one of the exhibits attached to your original declaration, Park 1.

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Is that right?
A. I think so. Yeah.
(Pause)
Q. Would both of your POSAs have been aware of Park 11?
A. Again, formulation scientist would know USP.
Q. I want to look at the last page that we have here, 2121.
A. Yes.
Q. On the left-hand column on the bottom, it says: Capsules, Powders, Lozenges, and Tablets?
A. Yes.
Q. Would your POSAs have been aware that when compounding capsules, for example, the pharmacist should prepare an amount of the total formulation sufficient to allow the prescribed amount or quantity to be accurately dispensed?
A. I think it's too general to me.
Could you make it a little more specific?
Q. I'm reading a sentence from this document.
I'm just asking if your POSA would

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agree with that sentence.
A. So tell me again which sentence you read?
Q. Sure. The one that begins: When compounding these dosage forms.
I did sub in "capsule" because it's one of the dosage forms, at least as I understand it, to be talking about.
A. So compounding means pharmacist make formulation for a specific patient.
So like the example we talked about, lidocaine -- if the question is deliver lidocaine 300 milligram, but it is a salt, you may have to consider how much total you have delivered.
But simply saying "deliver lidocaine salt HCl 300 milligram," then pharmacist will compound 300 milligram of salt, resulting in less than 300 milligram lidocaine.
Q. So if the pharmacist is aware that you are supposed to use 300 milligram lidocaine hydrochloride, they would compound 300 milligram lidocaine hydrochloride?
A. If that's the instruction, then they will just use as instructed.

Q. But if the instruction is "compound 300 milligrams lidocaine," and they are using the lidocaine hydrochloride, they would compound a higher amount, right?
A. Well, if the instruction said just "use 300 milligram lidocaine hydrochloride," then pharmacist will use 300 milligram lidocaine hydrochloride.
Q. Got that. Different question.
If the instruction said "use 300 milligrams lidocaine," but the pharmacist used lidocaine hydrochloride for the compounding, they would have to use a higher amount of the lidocaine hydrochloride, right?
A. If the instruction said "use 300 milligram pure lidocaine," then pharmacist will consider calculating how much pure -- how much salt form is necessary.
But before, the question was: If instruction simply said deliver -- make a formulation delivering lidocaine hydrochloride 300 milligram, then that will be 300 milligram, including salt.
Q. I hear you.
My question was not about lidocaine

hydrochloride.
And you added in there: Pure.
Is there a difference between if I just say "lidocaine" on its own and "pure lidocaine"?
A. Well, lidocaine -- depending on situation, you need to clarify exactly whether it is pure form or salt form, hydrate. So you need to be specific how much each drug is delivered.
Q. So unless I say "pure lidocaine," you would understand lidocaine could possibly include the salt or the hydrate.
Is that your testimony?
A. Yes, unless you specify pure lidocaine. Simply saying "lidocaine," it comes in different form, so that's possible.
MR. CALVOSA: Barring any questions from my good friend over here, we have nothing further.
MR. JAGOE: I have no questions.
MR. CALVOSA: Okay. Dr. Park, thank you very much for your time.
THE WITNESS: Thanks very much.
MR. CALVOSA: We appreciate it.

MR. JAGOE: Thanks.
THE VIDEOGRAPHER: The time is 2:11 p.m. We are off the record.
* * *
E N D O F P R O C E E D I N G
Time noted 2:11 p.m.
* * *

C E R T I F I C A T E

STATE OF NEW YORK
COUNTY OF NEW YORK

I, BRANDON RAINOFF, a Federal Certified Realtime Reporter and Notary Public within and for the State of New York, do hereby certify:
That KINAM PARK, Ph.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness.
I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.
IN WITNESS WHEREOF, I have hereunto set my hand this 7th day of June, 2019.

Jane Rose Reporting
BRANDON RAINOFF, FCRR, RMR, CRR

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NOTICE TO READ AND SIGN

This transcript was electronically distributed to KIRKLAND & ELLIS LLP to forward to witness.

ACKNOWLEDGMENT OF DEPONENT

I, Kinam Park, Ph.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____________ _____________________________
Date Kinam Park, Ph.D.

Signed and subscribed to before me this
______day of______________________, 2019.

____
Notary Public
My Commission expires:____________________

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INDEX OF EXHIBITS

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This transcript was electronically distributed to KIRKLAND & ELLIS LLP to forward to witness.

ACKNOWLEDGMENT OF DEPONENT

I, Kinam Park, Ph.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

June 26, 2019
Date

Kinam Park
Kinam Park, Ph.D.

Signed and subscribed to before me this
26 day of June, 2019.

Notary Public

My Commission expires: 4/30/27

Jeremy G Simmons
Notary Public Seal State of Indiana
Tippecanoe County
Commission Number NP0720065
My Commission Expires 04/30/2027

PAGE	LINE	CHANGE		REASON
14	10	"retained a"	to "retainer"	Typo
14	13	"retained a"	to "retainer"	Typo
19	6	"called"	to "calls"	Typo
19	18	"throughout"	to "drug"	Typo
20	2	"in"	to "and"	Typo
20	15	"for"	to "put"	Typo
51	6	"can you"	to "you can"	Typo
55	8	"resort"	to "adsorb"	Typo
71	24	"Extent friction"	to "Extent of friction"	Typo
77	6	"resorb in"	to "absorb"	Typo
77	16	"in pouring"	to "you pour"	Typo
100	16	"opine"	to "opined"	Typo
102	12	"not equilibrium"	to "in equilibrium"	Typo
120	22	"take"	to "takes"	Typo